UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,667	09/06/2000	Karen L. Briegs	ID01065Q	8973

24265 7590 06/06/2003

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER
PASS, NATALIE

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/655,667	BRIEGS ET AL.	
	Examiner	Art Unit	
	Natalie A. Pass	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2000 & 17 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *18,39-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 19-38, 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Notice to Applicant

1. This communication is in response to the application filed 06 September 2000 and the Response to Restriction Requirement filed 17 March 2003. Claims 1-45 are pending. Claims 1-17, 19-38, 42-45 have been elected without traverse. Claims 18, 39-41 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The abstract of the disclosure is objected to because it exceeds 150 words in length and is not limited to a single paragraph Correction is required. See MPEP § 608.01(b).

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 35-36, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) As per claims 35-36 Applicant recites in claim 35 on line 2 " [...] user processors located [...] in the geographical area [...]" and in claim 36 on lines 2-3 " [...] processors and subsidiary databases [...] located in respective geographical areas that are different from the geographical area in which [...]". It is not clear what distances or geographical boundaries are required for the processors and the databases to be in the same or different geographical areas. For the purposes of applying art, the Examiner is giving these limitations the broadest interpretation, namely that the clinical trial sites and subsidiary databases are in the same location or are remote from each other.

(B) Claims 37-38 incorporate the deficiencies of claim 36 through dependency and are therefore rejected.

(C) As per claim 42, Applicant recites "The clinical trial management system of claim 27 wherein there the plan is in the form of at least one lower level plan that forms part of a

higher and wherein the program automatically updates the display of the upper level plan and where an update in a lower level plan automatically update." This entire claim lacks antecedent basis, and it is respectfully submitted that the claim should have recited "The data acquisition and management system of claim 39 [...]," in which case this claim would have been drawn to a non-elected invention. Additionally, the claim language lacks clarity as words appear to be omitted. For the purposes of applying art, the Examiner is giving these limitations the broadest interpretation, namely that the clinical trial management system of claim 27 includes a plan, which can be automatically updated, and assuming that Applicant intends to amend the claim to properly depend upon claim 27.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 6-7, 11, 13, 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937.

(A) As per claim 1, Colon teaches a clinical trial management system comprising:

a main database of information concerning prior clinical trials and resources available to conduct future clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to

column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54) , the information concerning prior clinical trials being at least in part in the form of a protocol of (a) scheduled visits of a test subject to a treatment site, (b) measurement of prescribed physical attributes of the subject during the visits and (c) administration of at least one prescribed medical product to the subject during the visit to determine over time the subject's response thereto (Colon; Figure 4, column 1, lines 47-53, column 6, lines 1-14, column 6, line 58 to column 7, line 31);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43); and

at least one user or investigator processor in communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46).

Colon fails to explicitly disclose the protocol of a prior clinical trial being stored in said main database in the form of a software template; and

said user processor and main processor running a program that permits the design and tracking at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template to formulate a new clinical trial or event..

DeBusk teaches the protocol or standardization of a prior clinical trial or event being stored in said main database in the form of a software template or configurable object (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30); and

said user processor and main processor running a program that permits the design and tracking at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template or predesigned software object to formulate or create a new clinical trial or event (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-53, column 12, line 21 to column 13, line 34, column 14, line3 to column 15, line 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the clinical trial management system, of Colon to include the protocol of a prior clinical trial being stored in said main database in the form of a software template; and said user processor and main processor running a program that permits the design and tracking at said user processor of a clinical trial through access by said user processor to at least one software template in said main database and modification of the template to formulate a new clinical trial or event, as taught by DeBusk, with the motivation of providing an integrated information system for us in healthcare institutions for managing, optimizing and analyzing the use of resources within that institution utilizing a modular, component-ware software structure (DeBusk; column 7, lines 11-33).

(B) As per claims 6-7, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials

(Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

further including a communications link with said other databases and means for replicating or updating selected portions of the data in the other databases into the main database (Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products (DeBusk; column 14, line 46 to column 15, line 13).

(C) As per claims 11, 13, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein the program is in the form of modules (DeBusk; see at least Abstract, Figure 1, Figure 2, column 7, lines 40-58); and

wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial (Colon; column 2, lines 5-8, column 6, lines 39-50).

(D) Claim 43 differs from differs from claims 1 and 19 in that is a clinical trial management system comprising said user processor and main processor running a program that permits the input of information with regard to the completion of tasks forming a protocol for a

clinical trial and the tracking of the completion of the tasks at said user processor, a portion of said program printing forms determined by the data in the system rather than a clinical trial management system that stores the protocols of clinical trials in the form of a software template or a clinical trial management system comprising a subsidiary database and a subsidiary processor being in communication with a main processor to controlling replication of a portion of the data in the main database to said subsidiary database.

As per claim 43, Colon and DeBusk teach a clinical trial management system comprising:

a main database of information concerning resources available to conduct clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43);

at least one user or investigator processor in direct communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46), said user processor and main processor running a program that permits the input of information with regard to the completion of tasks forming a protocol for a clinical trial and the tracking of the completion of the tasks at said user processor, a portion of said program printing forms determined by the data in the system (Colon; column 1, line 35 to column 2, line 4, column 6, lines 21-30, column 6, line 39 to column 7, line 54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56).

The motivations for combining the respective teachings of Colon and DeBusk are as given in the rejection of claim 1 above, and incorporated herein.

8. Claims 2-5, 15-17, 19, 20-22, 23-24, 28, 32-38, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 and DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claims 1, 19, and 43 and further in view of Edelson et al, U.S. Patent Number 5, 737, 539.

(A) Claim 19 differs from claim 1 in that is a clinical trial management system comprising a subsidiary database and a subsidiary processor being in communication with a main processor to controlling replication of a portion of the data in the main database to said subsidiary database rather than a clinical trial management system that stores the protocols of clinical trials in the form of a software template.

As per claims 2, 19, Colon and DeBusk teach a clinical trial management system as analyzed and discussed above, comprising:

a main database of information concerning resources available to conduct clinical trials (Colon; see at least Abstract, Figure 1, Item 12, column 1, line 35 to column 2, line 4, column 2, line 58 to column 3, line 22, column 3, lines 15-23, column 6, lines 50-51, column 7, lines 45-54);

a main processor controlling access to said main database (Colon; Figure 1, Item 13, column 3, lines 24-43);

at least one user or investigator processor in direct communication with said main processor to negotiate access to said main database (Colon; Figure 1, Items 12, 18 and 21, column 1, lines 35-46), said user processor and main processor running a program that permits the design of a clinical trial or event in the form of a protocol of tasks to be completed and the tracking of the completion of the tasks in the protocol at said user processor (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

a subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 14, lines 53-56, column 15, lines 5-13);

a subsidiary processor controlling access to said subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 14, lines 53-56, column 15, lines 1-13);

at least one subsidiary user processor in communication with said subsidiary processor, said subsidiary processor and subsidiary user processor running the program so as to permit the design and tracking at said subsidiary user processor of a clinical trial or protocol based on data in said subsidiary database (Colon; column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56).

Colon and DeBusk fail to explicitly disclose

said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database.

Edelson teaches said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database (Edelson; column 48, lines 4-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon and DeBusk to include said subsidiary processor being in communication with said main processor to controlling replication of a portion of the data in the main database to said subsidiary database, as taught by Edelson, with the motivation of providing systems for clinical laboratory management, for medical record management for radiology management and the like, of providing novel professional data management systems that can yield comparable benefits in other professional spheres where professionals are responsible for solving client or customer problems, and of ensuring that all users in the network constantly share the same level of information (Edelson; column 7, lines 11-33, column 48, lines 4-24).

The motivations for combining the respective teachings of Colon and DeBusk are as given in the rejection of claim 1 above, and incorporated herein.

(B) As per claims 3-5, 15-16, 20-22, 32-33, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claims 1, 2, and 19 above,

wherein said subsidiary processor, subsidiary database and subsidiary user processor are located in a certain geographical location remote from the location of said main database and said main processor (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7,

lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein the portion of data replicated to said subsidiary database relates to clinical trials in said certain geographical location (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46);

wherein the portion of data in said subsidiary database includes at least one template of a clinical trial protocol previously created according to requirements prevalent in the certain geographical location (DeBusk; column 8, lines 5-20, column 10, line 29 to column 11, line 53, column 12, lines 21-31); and

wherein the portion of data in said subsidiary database can be altered by said subsidiary user processor and the data in the main database can be altered by said user processor (Colon; column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56), (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46);

wherein said main processor and said subsidiary processor periodically operate to synchronize the replicated and changed data at said main database and said subsidiary database, with changes at said main database predominating over changes at said subsidiary database (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46));

wherein the program running on said subsidiary processor includes a site management module for indicating the conditions at the certain geographical location, including the portion of

any protocol to be carried out in that geographical location (Colon; Abstract, Figure 1, Figure 4, column 1, line 47 to column 2, line 26, column 4, lines 60-65, column 5, lines 14-24), (Edelson, column 24, lines 40-59, column 38, lines 41-48, column 48, lines 47-64, column 52, lines 57-65); and

wherein information about the completion of tasks in the protocol at the certain geographical location are entered by the subsidiary user processor in the subsidiary database, and the site management module updates the portion of the protocol related thereto (Colon; Figure 3, column 1, line 35 to column 2, line 4, column 4, lines 26-36, column 6, lines 21-30, column 6, line 39 to column 7, line 54), (DeBusk; column 6, lines 33-67, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 26, line 56, column 15, lines 51-56).

(C) As per claims 17, 34, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claims 1 and 19 above, further including a portable processor running the program, said portable processor operating with said main processor to transfer or compile to the portable processor a copy of a portion of the main database related to a site for the clinical trial in a certain geographical area, said main processor locking the portion of the main database that was copied, said portable processor receiving information about the completion of tasks in the protocol at the certain geographical area and modifying the copy as a result thereof, and said portable processor operating with said main processor to transfer to or upload and update the main database with the modified copy of the data and to unlock that portion of the main database (Edelson; column 7, line 43 to column 8,

line 61, column 11, lines 21-27, column 43, line 48 to column 45, line 38, column 45, line 55 to column 46, line 61, column 47, lines 1-7, column 48, lines 4-31, 42-64).

(D) As per claims 23-24, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and discussed in claim 19 above, wherein said main processor and main database are in an organizational environment which includes other databases with specialized information useful in formulating clinical trials (Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

further including a communications link with said other databases and means for replicating or updating selected portions of the data in the other databases into the main database (Colon; column 2, line 58 to column 3, lines 22, column 5, lines 14-34, column 6, lines 21-43, column 6, lines 60-66, column 7, lines 26-61); and

wherein the other databases are one of a human resources database of personnel and location information, a finance database of budget authorization and cost information and a clinical supplies database of information on the availability of various clinical medical products (DeBusk; column 14, line 46 to column 15, line 13).

(E) As per claim 28, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above

wherein the program is in the form of modules (DeBusk; see at least Abstract, Figure 1, Figure 2, column 7, lines 40-58).

(F) As per claims 35-38, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above.

wherein there are a plurality of user processors located at different clinical trial sites in the geographical area in which the main processor and main database are located (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein there are a plurality of subsidiary processors and subsidiary databases each located in respective geographical areas that are different from the geographical area in which the main processor and main database are located (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56);

wherein there are a plurality of subsidiary user processors located in each geographical area in which a subsidiary processor and subsidiary database are located, said plurality of subsidiary user processors being connected to the subsidiary processor in their respective geographical area (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines

45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56); and

in which the geographical areas are countries (Colon; column 2, line 58 to column 3, line 10), (Edelson; column 47, lines 1-7, column 48, lines 60-64).

(G) As per claim 44, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 43 above

further including a subsidiary processor, subsidiary database and subsidiary user processor located in a certain geographical location remote from the location of said main database and said main processor (Colon; column 1, lines 35-62, column 2, line 58 to column 3, line 12, column 3, line 50 to column 4, line 22, column 5, lines 14-24, column 6, lines 21-32, column 7, lines 45-54), (DeBusk; column 6, lines 33-49, column 7, lines 40-59, column 8, lines 5-61, column 12, line 21 to column 13, line 34, column 14, line 3 to column 15, line 56); and

wherein a portion of data in the main database is replicated to said subsidiary database and relates to clinical trials in said certain geographical location (Edelson; column 7, lines 15-32, column 8, lines 4-10, column 47, lines 8-20, column 48, lines 4-46).

9. Claims 25-27, 29-30, 42, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731, DeBusk et al., U.S. Patent Number 5, 995, 937 and Edelson et al, U.S. Patent Number 5, 737, 539, as applied to claim 19 above, and further in view of Umen et al, U.S. Patent Number 5, 734, 883.

(A) As per claim 25, Colon, DeBusk and Edelson teach a clinical trial management system as analyzed and disclosed in claim 19 above.

Colon, DeBusk and Edelson fail to explicitly disclose a system further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Umen teaches a system further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Umen; see at least Figure 3, Items 56c, 66, Figure 6, Figure 7, column 10, lines 22-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon, DeBusk and Edelson to include further including a display at the user processor and subsidiary user processor which are operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as taught by Umen, with the motivation of providing an automated system for organizing text and details associated with drug studies into a convenient database, and for integrating such information in the form of standard documents, providing a system that would also be desirable to be adapted for use in preparing documentation, such as Product License Applications or Establishment Licenses, in connection with studies relating to medical devices or to biological agents, such as viruses, sera, toxins, antitoxins, and the like, and providing a system that would be adapted to arranging such

information in the form of documents that are compliant with each of the various manners which may be prescribed for such documents by U.S. or foreign regulatory agencies (Umen; column 2, lines 46-61).

(B) As per claims 26-27, 29-30, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above

wherein said users processor and subsidiary user processors can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial (Umen; see at least Figure 3, Items 58, 60, 98c, column 3, lines 51-56, column 4, lines 13-20);

wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed (Umen; column 7, lines 23-55, column 8, line 66 to column 9, line 42, column 17, line 16 to column 18, line 50);

wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display (Umen, Figure 3, Item 66, Figure 5, column 5, lines 29-63, column 7, line 7 to column 8, line 8); and

wherein the program includes a reports module that generates messages to personnel concerning actions to take to advance the trial (Colon; column 2, lines 5-8, column 6, lines 39-50); and

(C) As per claim 42, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above

wherein there the plan is in the form of at least one lower level plan that forms part of a higher and wherein the program automatically updates the display of the upper level plan and where an update in a lower level plan automatically update (Edelman; column 14, lines 53-60, column 15, lines 35-45, column 26, lines 19-28, 55-67), (Umen; Abstract, column 1, line 40 to column 2, line 62, column 19, lines 25-55, column 7, line 55 to column 8, line 22).

(D) As per claim 45, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 19 above

wherein the system manages a plurality of clinical trials with separate protocols, at least some of the separate protocols having major tasks made up of a plurality of minor tasks that are common to them, and wherein the program automatically indicates the completion of a common major task in the separate protocols when all of the minor related tasks are completed (Colon; column 1, lines 47-53, column 6, line 58 to column 7, line 51), (Umen; Figure 3, column 6, line 59 to column 7, line 40, column 13, line 1 to column 14, line 67, column 15, line 64 to column 16, line 65); (Edelson; column 8, lines 46-50, column 13, lines 35-49, column 28, line 43 to column 29, line 35, column 48, lines 5-24).

10. Claims 8-10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claim 1 above, and further in view of Umen et al, U.S. Patent Number 5, 734, 883.

(A) As per claim 8, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above.

Colon and DeBusk fail to explicitly disclose a system further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task.

Umen teaches a system further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task (Umen; see at least Figure 3, Items 56c, 66, Figure 6, Figure 7, column 10, lines 22-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the collective teachings, of Colon and DeBusk to include further including a display at the user processor which is operative to display the clinical trial protocol as a list of visits in sequence that form the protocol, with minor tasks that make up a major task indented under the major task, as taught by Umen, with the motivation of providing an automated system for organizing text and details associated with drug studies into a convenient database, and for integrating such information in the form of standard documents, providing a system that would also be desirable to be adapted for use in preparing documentation, such as Product License Applications or Establishment Licenses, in connection with studies relating to medical devices or to biological agents, such as viruses, sera, toxins, antitoxins, and the like, and providing a system that would be adapted to arranging such information in the form of documents that are compliant

with each of the various manners which may be prescribed for such documents by U.S. or foreign regulatory agencies (Umen; column 2, lines 46-61).

(B) As per claims 9-10, 12, Colon, DeBusk and Umen teach a clinical trial management system as analyzed and disclosed in claim 1 above

wherein said users processor can used to input information concerning completion of tasks in the protocol, and the display is updated to show progress of the trial (Umen; see at least Figure 3, Items 58, 60, 98c, column 3, lines 51-56, column 4, lines 13-20);

wherein the program automatically indicates the completion of a major task when all of its minor related tasks are completed (Umen; column 7, lines 23-55, column 8, line 66 to column 9, line 42, column 17, line 16 to column 18, line 50); and

wherein the program includes a reports module that generates reports of the status of the trial for presentation on the display (Umen, Figure 3, Item 66, Figure 5, column 5, lines 29-63, column 7, line 7 to column 8, line 8).

11. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731 in view of DeBusk et al., U.S. Patent Number 5, 995, 937 as applied to claim 1 above, and further in view of Official Notice.

(A) As per claim 14, Colon and DeBusk teach a clinical trial management system as analyzed and disclosed in claim 1 above.

Colon and DeBusk fail to explicitly disclose a system wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

The Examiner takes Official Notice that sending a message to a provider of supplies to inform it of supplies needed is well known in the art, and in addition that it would be obvious to send a message to a provider of clinical supplies for the trial to inform it of medical products needed for the trial in a system which comprises an information system incorporating software for supply, scheduling and resource utilization management in the health-care environment (DeBusk; Abstract, column 1, lines 5-10, column 3, lines 18-25, column 6, lines 33-45, column 7, lines 11-24, column 11, lines 12-30, column 12, lines 47-54) with the motivation of streamlining the supply process while insuring that the process results in the best balance between waste minimization and standardization, in addition to the ultimate requirement that all of the supplies required during a procedure are actually available when the procedure is conducted, and of providing the customer and the suppliers with a framework within which the suppliers can respond very rapidly to an order, while minimizing inventory, which minimizes inventory carrying costs, the risk that inventory will expire before use, tied-up capital and the skilled labor necessary to maintain the inventory and pull it for each procedure (DeBusk; column 3, lines 18-25, column 5, lines 47-52, column 11, lines 12-53). In addition, the skilled artisan motivated to notify a provider of clinical supplies of required medical products within the DeBusk invention would have likewise found it obvious to send a message to deliver that information as described above. Moreover, the Examiner respectfully submits that Applicant is not the first to invent sending messages to suppliers as described above. The use of messages to

suppliers as described above was well established in the prior art and the courts have held that even if a patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

12. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al., U.S. Patent Number 5, 991, 731, DeBusk et al., U.S. Patent Number 5, 995, 937, Edelson et al, U.S. Patent Number 5, 737, 539, and Umen et al, U.S. Patent Number 5, 734, 883 as applied to claim 25 above and further in view of Official Notice.

(A) As per claim 31, Colon, DeBusk, Edelson and Umen teach a clinical trial management system as analyzed and disclosed in claim 25 above.

Colon, DeBusk, Edelson and Umen fail to explicitly disclose a system wherein at least one of the messages is to a provider of clinical supplies for the trial to inform it of the medical products needed for the trial.

The Examiner takes Official Notice that sending a message to a provider of supplies to inform it of supplies needed is well known in the art, and in addition that it would be obvious to send a message to a provider of clinical supplies for the trial to inform it of medical products needed for the trial in a system which comprises an information system incorporating software for supply, scheduling and resource utilization management in the health-care environment (DeBusk; Abstract, column 1, lines 5-10, column 3, lines 18-25, column 6, lines 33-45, column

7, lines 11-24, column 11, lines 12-30, column 12, lines 47-54) with the motivation of streamlining the supply process while insuring that the process results in the best balance between waste minimization and standardization, in addition to the ultimate requirement that all of the supplies required during a procedure are actually available when the procedure is conducted, and of providing the customer and the suppliers with a framework within which the suppliers can respond very rapidly to an order, while minimizing inventory, which minimizes inventory carrying costs, the risk that inventory will expire before use, tied-up capital and the skilled labor necessary to maintain the inventory and pull it for each procedure (DeBusk; column 3, lines 18-25, column 5, lines 47-52, column 11, lines 12-53). In addition, the skilled artisan motivated to notify a provider of clinical supplies of required medical products within the invention of Colon, DeBusk, Edelson and Umen would have likewise found it obvious to send a message to deliver that information as described above. Moreover, the Examiner respectfully submits that Applicant is not the first to invent sending messages to suppliers as described above. The use of messages to suppliers as described above was well established in the prior art and the courts have held that even if a patent does not specifically disclose a particular element, said element being within the knowledge of a skilled artisan, the patent taken in combination with that knowledge, would put the artisan in possession of the claimed invention. *In re Graves*, 36 USPQ 2d 1697 (Fed. Cir. 1995).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references, Herren et al, U.S. Patent No. 6,108,635, Le Rue, U.S. Patent No. 5,694,469, Prokoski, U.S. Patent No. 6, 173, 068, and the article teach the environment of clinical trials management and database maintenance.

Herren et al, U.S. Patent No. 6,108,635, teaches an integrated disease information system, including clinical trials design.

Le Rue, U.S. Patent No. 5,694,469, teaches a method and system for disseminating stored programs and data including database access codes and locking databases.

Prokoski, U.S. Patent No. 6, 173, 068, teaches medical diagnostic techniques involving clinical trials and protocols.

Lamb, Kristen A. Bridging the Gap between Drug Discovery and Market. Introduction: The Rise of Contract Research Organizations. Feb. 2, 1998. [Retrieved on June 2, 2003]. Retrieved from Internet. URL: <http://leda.law.harvard.edu/leda/data/203/klamb.pdf>

14. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington D.C. 20231

or faxed to: **(703) 305-7687**.

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication.

After Final communications should be labeled "Box AF."

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, Seventh Floor (Receptionist).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (703) 305-3980. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (703) 305-9588. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 308-1113.

Natalie A. Pass

June 2, 2003

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600